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Battelle Docket No. 15896US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lipp, Brian A.	Art Unit: 3771
Serial No: 10/763,040	Examiner: Dixon, Annette
Filed: January 21, 2004	
For: GAS OR LIQUID FLOW SENSOR	

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Dear Sir:

DECLARATION OF WILLIAM C. ZIMLICH, JR. UNDER 37 CFR 1.132

I, William C. Zimlich, Jr., 5653 Morlich Square, Dublin, Ohio 43017, United States of America, hereby declare the following:

- I am Chief Executive Officer of Activaero America, Inc which is a U.S. based subsidiary of Activaero, GmbH located in Gemünden, Germany; in this capacity, I work with clients in the development of feasibility and clinical trials with Activaero's AKITA technology, which is a precise pulmonary drug delivery system; development of a respiratory disease management systems combining drug delivery with patient monitoring for severe asthma, COPD and cystic fibrosis.

- I have nine (9) issued US patents and multiple pending US patents as well as numerous issued and pending foreign patents.

- I am an author or co-author of over 18 papers, abstracts and scientific presentations relating to pulmonary drug delivery and devices used for pulmonary drug delivery.

- A comprehensive listing of my education, training, and accomplishments is set forth in my *Curriculum Vitae* attached to this Declaration.

- I have read and understand the claims ("Invention Claims") of the Lipp application (USSN 10/763,043) as amended in Applicant 's Response Dated October 22, 2008 and in particular Claim 1.

- I have read and understand the specification and claims of US 5,311,875 to Stasz.

- I have read and understand that portion of Examiner's Office Action, dated 06/26/2008 where Examiner rejects the Invention Claims as being anticipated by US 5,311,875 (Stasz).

- Based on my review of the Stasz patent and of the Invention Claims, I find the following significant differences between the invention described by the Stasz patent the invention of Claim 1 of Lipp:

    - Claim 1 of Lipp describes a sensor which contains a non-conductive flexible substrate. The flexible substrate disclosed by the Stasz reference is a conductive, "dynamic" film substrate which has both pyroelectric and piezoelectric properties and which produces a voltage output due to changes in temperature.

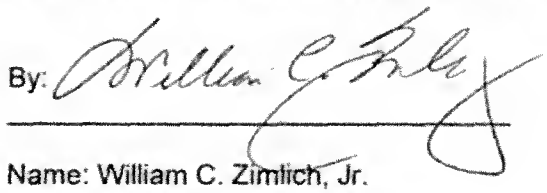
    - Referring to Fig. 1A of Lipp, Claim 1 of Lipp requires at least one "flexible lead" (16) connecting the substrate (13) to a mounting portion (18) of the sensor. The flexible lead (16), and the mounting portion (18) are areas of the non-conductive film substrate (13). The flexible substrate and the flexible lead are displaceable in the presence of a stream of moving gas or liquid causing a flexure of the resistive ink transducer (22) and changing the electrical value of the transducer. In my opinion, these elements of Claim 1 of Lipp are not described or claimed in the Stasz reference.

    - A critical element of the sensor described in the Stasz patent (shown in Fig. 1 and especially in Fig. 2), requires areas of "metallization" (18 and 20) to be present on both sides of the pyroelectric/piezoelectric film. These areas of metallization act as electrodes to conduct the low frequency voltage developed by the polyvinylidene fluoride film (PVDF) transducer due to changes in temperature to the circuit means. The sensor described in Claim 1 of Lipp does not contain any areas of metallization.

    - The transducer element of the Stasz reference detects changes in temperature and changes in applied pressure due to the direct impingement of the expired breath of a human or animal. Applicant's transducer element detects neither a change in temperature nor a change in direct pressure. In Applicant's claimed invention, a stream of moving gas (e.g., air) or liquid displaces the flexible substrate which in turn causes the resistive ink transducer applied to an area of the flexible substrate to bend or crack changing its electrical value.

    - Based on education, experience, and my review of the Stasz patent and of the Invention Claims, it is my opinion that the Stasz patent does not describe all of the elements of the Invention Claims and especially of Claim 1 of the Lipp Application (USSN 10/763,043).

I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: October 22, 2008 By: 

Name: William C. Zimlich, Jr.

WILLIAM C. ZIMLICH, JR.
CURRICULUM VITAE

MEDICAL PRODUCT DEVELOPMENT

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PROFESSIONAL SYNOPSIS

Thoroughly experienced in Medical Product Development Engineering, Mr. Zimlich has demonstrated the ability to develop a product form idea inception through research and development and into cost effective mass production. Widely experienced in bringing together cross-functional teams of industrial designers, CAD tool specialists, engineers, scientists, manufacturing and regulatory personnel, he has successfully brought complex medical and pharmaceutical products to market in a timely and economic manner.

Mr. Zimlich has ventured outside engineering and worked as a Product Manager in the medical device arena. While in this position, he gained experience in Marketing Management, New Business Development, Strategic Planning, Business Forecasting, and Pricing Strategies. As a product manager, he has spent time in the field with health care professionals developing sales and new product ideas.

During his 24 year career, Mr. Zimlich has gained a working knowledge of electronic assemblies through the development of video imaging systems, CPUs, keyboards, power supplies, robotic systems, drug delivery devices and other microprocessor based products and opto-mechanical devices. Considerable experience in materials including thermoplastics, metals, ceramics and composites. Designed for manufacturing by injection molding, stamping, die casting, extrusion, welding and CNC machining.

To further his experience base, he has taken on manufacturing management roles for two companies. He has set up ISO compliant MRP, inventory and scheduling systems. He has also done assembly line layout and plant design, and he has managed hourly personnel along with manufacturing engineers. This experience has proven itself as a valuable aid in brining products to market quickly and effectively.

Mr. Zimlich was part of the founding executive team establishing a separate private specialty pharmaceutical company with two key respiratory technology platforms. Managed multiple big pharma sponsored development programs. Successfully raised $25 million in a venture capital based series "B" round.

Traveling extensively around the world, he is capable of conducting business and coordinating projects both domestic and international.

EMPLOYMENT AND EXPERIENCE

ACTIVAERO AMERICA, INC., Dublin, Ohio 2006-Present
Chief Executive Officer
Lead American Business and Technical Development for U.S. based subsidiary of Activaero, GmbH located in Gemünden, Germany. Actively work with clients developing feasibility and clinical trials with AKITA technology, a precise pulmonary drug delivery device. Developing a Respiratory Disease Management System combining drug delivery with patient monitoring for severe Asthma, COPD and Cystic Fibrosis. Responsible for organization development , operations and profit and loss.

MEDICAL DEVICE CONSULTANT 2004-2006
Design and development of Inhalation Delivery Devices including project management, design control documentation, experimental design, regulatory planning and manufacturing assessment. Currently completing the development a pivotal trial device that will be utilized to safely deliver aerosolized chemotherapy agents reproducibly and accurately. Other activities include North American distributor of AKITA pulmonary delivery devices for Activaero GmbH, Gauting, Germany and Respiratory Device Technology assessment for Pulmatrix, Inc. in Boston, MA.

VENTAIRA PHARMACEUTICALS, INC., formerly BattellePharma, Inc. 2000-2004
Vice President of Device Product Development
Member of the founding and executive management team of a pre-public specialty pharmaceutical company, and a corporate officer. Responsible for the development and commercialization of the core technology, Mystic™, based on electrohydrodynamics for pulmonary drug delivery. Staffed both engineering and aerosol science department to bring three devices to clinical trials; an infant inhaler, an adult hand-held inhaler and a bench top clinical pulmonary drug delivery device. The technical and manufacturing issues had been methodically solved and a strategy developed for moving the product toward mass production.

BATTELLE MEMORIAL INSTITUTE, Columbus, Ohio 1997-2000
Vice President, Device Product Development, Healthcare Market Sector
Responsible for research and development of pulmonary drug delivery devices. Responsible for the incubation of electrohydrodynamic technology to clinical relevance to assure commercial viability of potential spin off company.

Program Director
Responsible for 200+ development team. Coordinated research and development activities to bring about a working prototype that early clinical trial results demonstrated the highest reported efficiency for administering pulmonary drugs. Activities supervised included formulation, statistical modeling, aerosol characterization, microbial integrity, and the industrial, mechanical and electrical design of this medical device. The development of this device has been in accordance to the medical device directive as regulated by the FDA.
Additional Responsibilities:

- Advisory Board Chair for the development of a Continuous Positive Airway Pressure (CPAP) device for use in the home healthcare market.
- Lead Mechanical Engineer for autologous fibrin sealant surgical device review.

MEDEX, INC., Dublin, Ohio 1992-1997
Publicly traded Medical products Manufacturer

Marketing Manager, Critical Care Devices
Responsible for profitability, strategy development, new application development, advertising, pricing and promotion for cardiac catheterization products and drug delivery devices. Worked closely with Research and Development in the specification and development of new products utilizing the latest available technology.

Derivative Products Engineering Manager
Responsible for Fast Track product development. Formed the Derivative Products Team and brought over 120 different new medical products to market while complying with GMPs and design controls. Developed a shortened design control path for Class II products that did not require a 510k in order to meet customers' timely product needs.

AMS PLASTICS, INC., El Cajon, California 1991-1992
San Diego's largest injection molder.

Director of Operations
Responsible for day-to-day molding and assembly operations as well as managing new product development. Successfully guided Medical, Biotech and Electronic device projects from the design stage, into tooling and then onto production. Selected new materials, processes and machines to reduce costs while improving quality.

STRATAGENE CLONING SYSTEMS, La Jolla, California 1988-1991
Rapidly growing biotech firm.

Director of Manufacturing
Responsible for purchasing, material control, assembly personnel and manufacturing engineering for both complex electromechanical devices as well as laboratory disposables.

Instrumentation Manager
Successfully staffed and managed a product development engineering group to bring 35 new products to market. Projects ranged from injection molded disposable to microprocessor based electromechanical laboratory instruments.

CAMBRIDGE AUTOMATION, Cerritos, California 1986-1988
International product development firm in the primary areas of injection molding, tooling, and electronic assembly.

Engineering Manager
Responsible for the design and development electronic packaging of medical, communication and computer industries that were then produced in the Pacific Rim. Designed and followed up the construction of over 40 injection/die cast molds constructed in Asia.

CHRYSLER CORPORATION, Detroit, Michigan 1984-1986
Product Development Engineer
Interfaced with the design studio to establish production techniques to meet styling requirements and corporate *fit and finish* goals of exterior parts. Led a group of draftspeople who did layouts and detail drawings of stampings, extrusions, injection molded parts and die-castings and followed these designs through to manufacturing.

EDUCATION

MBA program, partial, UNIVERSITY OF DETROIT, Detroit, Michigan
BS, in Mechanical Engineering, THE OHIO STATE UNIVERSITY, Columbus, Ohio

ISSUED PATENTS

- U.S. Patent 4629232 5 mph Bumper/Molding System (Issue Date 12/16/86)
- U.S. Patent 5288647 Irradiation of Biological Specimen with UV light (Issue Date 02/22/94)
- U.S. Patent 5395591 Apparatus of UV irradiation of DNA (Pub. Date 03/07/95)
- U.S. Patent 5814523 Method of Irradiating Biological Specimens (Issue Date 09/29/98)
- U.S. Patent 6269810 Pulmonary Dosing System and Method (Nebulizer useful for aerosolization of anticancer drugs (Issue Date 08/07/01)
- U.S. Patent 6368079 Piezoelectric Micropump (Issue Date 04/09/02)
- U.S. Patent 6397838 Pulmonary Aerosol Delivery Device and Method (Issue Date 06/04/02)
- U.S. Patent 6796303 Pulmonary Aerosol Delivery Device (issue Date 9/28/04)
- U.S. Patent 6805118 Pulmonary Dosing System and Method (Issue Date 10/19/04)

Plus multiple pending patents

AWARDS

R&D 100 Award for Mystic Infant Inhaler-Lead Inventor – 2003

PUBLICATIONS

Ding, J.Y. et.al., *Measurement of Particle Size Distribution from Metered Dose Inhalers by Malvern Diffraction Particle Sizer*, AAPS Annual Meeting and Exposition, Indianapolis, Indian, April 25, 2000.

Ding, J.Y., et.al., *Performance Evaluation of the PARI LC Nebulizer using different Nebulization Pressures*, Respiratory Drug Delivery VII, pp. 349-351, April, 2000.

Ding, J.Y., Zimlich, W.C., Placke, M.E., 2001 *Encyclopedia of Pharmaceutical, Chapter: Inhalation, Liquids,* pp. 1545-1572.

Placke, M.E., Zimlich, W.C., *Developing an Advanced Pulmonary Delivery Technology: Leveraging Engineering Challenges into Clinical Opportunities*, Drug Delivery Technology, vol. 2, no. 4, pp. 40-46, June, 2002.

Ding, J.Y., et.al., *Correlation of Particle Size Distribution Measurements Between Optical and Inertial Impacation Techniques Using an Ethanolic Drug Formulation for Inhalation*, Respiratory Drug Delivery VII, vol. 2., pp. 359, May, 2002.

ABSTRACTS AND SCIENTIFIC PRESENTATIONS

Zimlich, W.C., et.al., *The Development of a Novel EHD Pulmonary Delivery Device* presented at Respiratory Drug Delivery to the Lungs VII, Tarpon Springs, Florida, pp. 241-246, April, 2000.

Zimlich, W.C., *Using Advanced Pulmonary Delivery Technology to Improve Clinical Outcomes* presented at The Australian & New Zealand Society of Respiratory Science, Brisbane, Australia, March 19, 2001.

Zimlich, W.C., *Advanced Pulmonary Delivery Technology to Improve Clinical Outcomes* presented at the 6th International Drug Delivery Technolgoies & Deal-Making Summit, Princeton, New Jersey, July 27, 2001.

Placke, M.E., et.al., *Targeted Aerosol Therapy for the Treatment of Lung Cancer*, Respiratory Drug Delivery VIII, Tucson, Arizona, vol. 1, pp. 15., May, 2002.

Zimlich, W.C., et.al., *Development of Multiple Clinical and Commercial Applications Using Mystic™ Inhalation Delivery Technologies*, presented at Respiratory Drug Delivery VIII, vol. 2, pp. 363, May, 2002.

Ding, J.Y., et.al., *Delivery of Chemotherapy Agent for Cancer Treatment via Nebulization*, presented at Respiratory Drug Delivery VII, Tucson, Arizona, vol. 2, pp. 359, May, 2002.

Placke, M.E., et.al., *Inhalation Aerosol Therapy for the Treatment of Lung Cancer*, International Aerosol Conference, September, 2002.

Ding, J.Y., et.al., *Development of an Efficient Infant/Pediatric Inhalation Device for Treatment of Respiratory Diseases*, International Aerosol Conference, September, 2002.

Zimlich, W.C., *Aerosol Delivery* presented at the Formulation Development of BioPharmaceuticals Conference, North Carolina Biotechnology Center, May 17, 2007.

Zimlich, W.C., *Novel Approaches to Enhance the Pulmonary Delivery of Biotherapeutics* presented at the 2nd Annual Drug Delivery Conference, San Diego, CA June 8, 2007.

Scheuch, G., et.al., *Low Variability Lung Delivery of Drugs: Novel Delivery Technology and Compliance Studies with Low Molecular Weight Heparin and Antibiotics*, Respiratory Drug Delivery 2008, Book 1, pp. 57, May, 2008.

Roeder, S., et.al., *Improvement of Asthma Therapy in Children with Adequate Spacers,* American Thoracic Society Annual Conference, Toronto, Canada, June, 2008.

Zimlich, W. C., et.al., *Combination of Electronically Controlled Breathing Pattern and Improved Nebulizer Technology Reduces Treatment Time,* American Thoracic Society Annual Conference, Toronto, Canada, June, 2008.